

A study of the reliability and validity of the Chinese version of the Nociception Coma Scale–Revised

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Abstract

Objective: The aim of the study was to check on the reliability and validity of the translated version of Nociception Coma Scale–Revised.

Design: Prospective psychometric study.

Setting: Rehabilitation and neurology unit in hospital.

Subjects: Patients with prolonged disorders of consciousness.

Interventions: None.

Main measures: The original English version of the Nociception Coma Scale–Revised was translated into Chinese. The reliability and validity were undertaken by trained raters. Intraclass correlation coefficients were used to assess inter-rater reliability and test–retest reliability. Cronbach’s alpha test was used to investigate internal consistency. Spearman’s correlation was used to calculate concurrent validity. The Coma Recovery Scale–revised was used to assess the consciousness of patients.

Results: Eighty-four patients were enrolled in the study. Inter-rater reliability of the Chinese version of Nociception Coma Scale–Revised was high for total scores and motor and verbal subscores and good for facial subscores. Test–retest reliability was high for total score and for all subscores. Analysis revealed a moderate internal consistency for subscores. For the concurrent validity, a strong correlation was found between the Nociception Coma Scale–Revised and the Face, Legs, Activity, Cry, and Consolability behavioral scale for all patients. A moderate correlation was found between the Nociception Coma Scale–Revised and the Coma Recovery Scale–revised scores for all patients.

Conclusion: The Chinese version of Nociception Coma Scale–Revised has good reliability and validity data for assessing responses to pain in patients with prolonged disorders of consciousness.

Keywords

Nociception, prolonged disorders of consciousness, pain, minimally conscious state, unresponsive wakefulness syndrome

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Introduction

The assessment and early detection of pain is critical for adequate pain management and the pharmacological treatment of pain in a clinical setting. According to the International Association for the Study of Pain, pain is defined as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” and nociception as “the neural process of encoding noxious stimuli.”¹ However, some researchers have shown that the response to pain is often underestimated by clinicians and caregivers, especially in persons with cognitive impairments who are unable to communicate.² To prevent under-assessment in this population, several tools have been developed to assess the ability to perceive pain, such as the Face, Legs, Activity, Cry, and Consolability³ and the Non-Communicative Patient’s Pain Assessment Instrument.⁴

Patients with prolonged disorders of consciousness, such as unresponsive wakefulness syndrome (formerly known as vegetative state)^{5–7} and minimally conscious state,⁸ following severe brain injury are particularly challenging to assess. Previous studies have indicated that these patients may retain some capacity for pain responses.^{9,10} However, they cannot report the experience of pain and it is not known whether they have any perception or experience. Thus, there were various measures existed to assess pain based on behavioral observations. The Nociception Coma Scale–revised is one such measure, which is intended to help record the responses to painful stimuli.^{11,12} However, it has not yet been studied in a Chinese population or with a Chinese version. The aim of this study was to validate a Chinese version of the Nociception Coma Scale–revised in order to make this tool available for the Chinese clinical setting and to contribute to further development of pain assessment and management in China.

Methods

This study has been registered in a clinical trials registration, and the Clinical Trials.gov number is NCT03494218. All patients’ relatives and caregivers

were informed about the experimental procedure and written informed consent was signed. The Ethical Committee of Hangzhou Normal University provided approval for the present study. The study was conducted from January 2018 to August 2019 and comprised the translation, evaluation, and validation.

The guidelines of the Nociception Coma Scale–Revised have been translated from the original English into Chinese by three authors who are native Chinese speakers and are experts in the field of prolonged disorders of consciousness. The authors were highly trained in the use of the original version of the Nociception Coma Scale–Revised by several experts from the team who developed the original scale. To detect errors and ensure that there was no misinterpretation between the translated and the original version, the Chinese-translated version (including the administration and scoring guidelines and record forms) was sent to three professional translators with English as their native language and a proficient knowledge of Chinese for a back-translation into English. Discrepancies were quickly resolved by discussion, and a consensus was reached among authors. The final Chinese version of the Nociception Coma Scale–Revised was thus finalized (see Supplemental Appendix 1). The Nociception Coma Scale–Revised consists of three subscales assessing motor, verbal, and facial responses, and each subscale score ranges from 0 to 3.

Individuals were recruited from the neurology unit of the Affiliated Hospital of Hangzhou Normal University (Zhejiang, China), the Rehabilitation unit of Wujing Hospital of Hangzhou (Zhejiang, China), the Shanghai Yongci Rehabilitation Hospital (Shanghai, China), and the Taizhou Hospital of Zhejiang Province (Zhejiang, China).

Inclusion criteria were as follows: (1) age ≥ 18 years old; (2) no administration of neuromuscular blockers, painkilling drugs, or sedation within 24 hours of enrollment; (3) the presence of periods of eye-opening; and (4) diagnosis of prolonged disorders of consciousness, based on behavioral assessments using Coma Recovery Scale–Revised.

Exclusion criteria were as follows: (1) documented history of prior brain injury; (2) psychiatric

or neurologic illness; (3) neuromuscular blocking agents, painkilling drugs, or sedative drugs administered within 24 hours of enrollment; and (4) documented history of a prior coma, critical illness, or unstable medical condition.

Patients with prolonged disorders of consciousness were divided into unresponsive wakefulness syndrome and minimally conscious state based on the behavioral assessment results of Coma Recovery Scale–Revised.^{13–16} In order to ensure a sufficient level of arousal, all scales were administered while patients showed spontaneous eye-opening; the arousal facilitation protocol of the Coma Recovery Scale–Revised was applied if necessary.

The Chinese version of the Nociception Coma Scale–Revised was administered to assess responses to noxious stimuli in each patient by two trained raters experienced in prolonged disorders of consciousness. The detailed assessment procedure of Nociception Coma Scale–Revised for each evaluation was as follows: Noxious stimuli (e.g. apply pressure on the nailbed of the figure of right and left hands) was administered by the rater for at least 5 seconds, stopped when a behavioral response was observed, and then patient's behavioral responses during the 10 seconds following each incident of noxious stimulus were recorded. The entire procedure lasted no longer than 5 minutes.

Each patient was assessed over two consecutive days. On day 1, two sessions were performed by two different raters (A and B) who were blind to the other rater's assessment within an interval of 6 hours. The order of administration was randomly selected. On day 2, responses of pain were assessed by rater A using Nociception Coma Scale–Revised together with the Face, Legs, Activity, Cry, and Consolability behavioral scale for each patient. Besides, the Coma Recovery Scale–Revised was administered to assess the level of consciousness in each patient by another experienced rater, before or after the administration of the Nociception Coma Scale–Revised and at a randomly selected time on day 2. The rater recorded patients' responses independently during the whole assessment process.

Behavioral responses according to the Nociception Coma Scale–Revised conducted by rater A and rater B on day 1 were compared to test

inter-rater reliability. The first evaluation of the Nociception Coma Scale–Revised by rater A on day 1 and the second evaluation by rater A on day 2 were used to analyze test–retest reliability. Scores from day 2 were recorded to test internal consistency of the Nociception Coma Scale–Revised. Furthermore, the Face, Legs, Activity, Cry, and Consolability behavioral scale scores and the Nociception Coma Scale–Revised scores on day 2 were used to assess concurrent validity. The Coma Recovery Scale–Revised scores and Nociception Coma Scale–Revised scores evaluated on day 2 were used to compare the correlation between the pain responses and levels of consciousness.

Descriptive statistics for patients were presented as means $\pm$ standard deviation (SD) or medians with inter-quartile ranges. Intraclass correlation coefficients (ICC) with 95% confidence intervals (95% CI)¹⁷ and the Bland–Altman plot¹⁸ were used to assess inter-rater reliability and test–retest reliability for Nociception Coma Scale–Revised total scores and subscores. Thresholds for ICC values were interpreted as follows: values of 0.59 or less were considered as low results, between 0.6 and 0.90 was considered good, and greater than 0.90 was considered high. Cronbach's alpha (α) test was used to investigate internal consistency.^{19,20} Internal consistency was considered unacceptable if α values were less than 0.5, poor for values between 0.5 and 0.59, questionable for values between 0.6 and 0.69, acceptable for values between 0.7 and 0.79, good for values between 0.8 and 0.89, and excellent for values between 0.9 and 1.0.^{21,22} Finally, the concurrent validity between Nociception Coma Scale–Revised scores and the Face, Legs, Activity, Cry, and Consolability behavioral scale scores was calculated using Spearman's rank correlation. The correlation between Nociception Coma Scale–Revised scores and consciousness level (the Coma Recovery Scale–Revised scores) was also calculated by Spearman's rank correlation. Spearman's rank correlation coefficient (r) of 0.39 or lower was considered weak, between 0.4 and 0.59 was considered moderate, and ≥ 0.60 was considered strong. Independent t tests were used to assess the difference between unresponsive wakefulness syndrome and minimally conscious state in Nociception

Table 1. Demographic and clinical data of patients with disorders of consciousness.

Characteristic	PDOC (<i>n</i> =84)	MCS (<i>n</i> =42)	UWS (<i>n</i> =42)
Gender (male/female), <i>n</i>	59/25	30/12	29/13
Median age at onset (range), years	53 (22–84)	54 (22–70)	52 (23–81)
Median time of postinjury (range), <i>m</i>	4 (1–22)	5 (1–16)	4 (1–22)
Etiology, <i>n</i>			
TBI	51	23	28
NTBI	33	19	14
Mean (SD) scores of CRS-R	7.26 (2.921)	9.45 (2.297)	5.07 (1.472)
Median scores of CRS-R (range)	7 (2–15)	9 (5–15)	5 (2–8)
Mean (SD) scores of NCS-R	3.95 (1.422)	4.69 (1.297)	3.21 (1.138)
Median scores of NCS-R (range)	4 (0–7)	5 (3–7)	3 (0–6)

PDOC: prolonged disorders of consciousness; MCS: minimally conscious state; UWS: unresponsive wakefulness syndrome; TBI: traumatic brain injury; NTBI: non-traumatic brain injury; SD: standard deviation; CRS-R: Coma Recovery Scale–Revised; NCS-R: Nociception Coma Scale–Revised.

Table 2. Inter-rater reliability of Nociception Coma Scale–Revised subscores.

NCS-R items	ICC value	95% CI	<i>P</i> value
Motor	0.951	0.941–0.968	<0.001
Verbal	0.979	0.968–0.986	<0.001
Facial	0.879	0.814–0.922	<0.001
Total score	0.961	0.941–0.975	<0.001

NCS-R: Nociception Coma Scale–Revised; ICC: intraclass correlation coefficients; 95% CI: 95% confidence intervals.

Coma Scale–Revised total scores. Statistical significance was set at $P < 0.05$.

Results

Eighty-four patients with prolonged disorders of consciousness were enrolled in the study. Demographic and clinical data of all patients are shown in Table 1.

Inter-rater reliability was high for the Nociception Coma Scale–Revised total scores and the motor and verbal subscores and good for the facial subscores, which indicated that Nociception Coma Scale–Revised could yield reproducible results across raters during assessment process (see Table 2 and Figure 1(a)).

Test–retest reliability for Nociception Coma Scale–Revised total scores by ICC was high. Regarding to the subscales, the reliability was high

for the motor subscores, the verbal subscores, and the facial subscores (see Table 3 and Figure 1(b)).

Internal reliability for Nociception Coma Scale–Revised by Cronbach's alpha (α) was moderate ($\alpha = 0.609$).

For the concurrent validity, a strong correlation was found between Nociception Coma Scale–Revised and Face, Legs, Activity, Cry, and Consolability behavioral scale for total scores by Spearman's correlation coefficient ($r = 0.613$, $P < 0.001$) of all patients, a moderate correlation of patients with minimally conscious state ($r = 0.434$, $P = 0.004$), and a strong correlation of patients with unresponsive wakefulness syndrome ($r = 0.524$, $P < 0.001$; see Figure 2).

Furthermore, a significant difference in Nociception Coma Scale–Revised total scores was found between patients in unresponsive wakefulness syndrome and minimally conscious state ($t = 5.545$; $P < 0.001$, 95% CI = 0.947–2.006; see Figure 3). For all patients with prolonged disorders of consciousness, a moderate correlation was found between the Nociception Coma Scale–Revised and the Coma Recovery Scale–Revised for total scores ($r = 0.565$, $P < 0.001$); for patients with minimally conscious state, a weak correlation was found between the Nociception Coma Scale–Revised and the Coma Recovery Scale–Revised for total scores ($r = 0.268$, $P = 0.087$); for patients with unresponsive wakefulness syndrome, a moderate correlation was

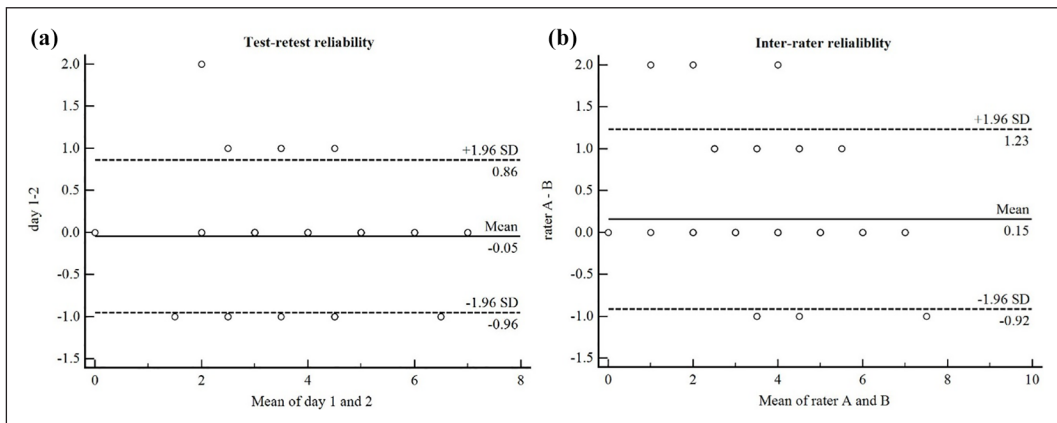


Figure 1. Bland–Altman plots for (a) test–retest and (b) inter-rater reliability. Plots illustrate the reliability between day 1 and day 2 of rater A and the reliability between rater A and rater B and identify possible outliers. Each sample is represented on the graph by conveying the mean value of the two assessments (x-axis) and the difference between those two assessments (y-axis). The mean difference is the estimated bias, and the SD of the differences measures the fluctuations around this mean (outliers being above 1.96 SD).
SD: standard deviation.

Table 3. Test–retest reliability of Nociception Coma Scale–Revised subscale scores.

NCS-R items	ICC value	95% CI	<i>P</i> value
Motor	0.925	0.884–0.951	<0.001
Verbal	0.981	0.970–0.987	<0.001
Facial	0.955	0.931–0.971	<0.001
Total score	0.971	0.956–0.982	<0.001

NCS-R: Nociception Coma Scale–Revised; ICC: intraclass correlation coefficients; 95% CI: 95% confidence intervals.

found between the Nociception Coma Scale–Revised and the Coma Recovery Scale–Revised for total scores ($r=0.414$, $P=0.006$; see Figure 4).

Discussion

This study translated the English version of Nociception Coma Scale–Revised into Chinese and validated the Chinese version. We found that the inter-rater reliability and the test–retest reliability were high for the Chinese version of Nociception Coma Scale–Revised. Moderate internal reliability and strong concurrent validity for this version were found in the present study. It is supporting that the

translated version is a suitable tool to record the responses to noxious stimuli for patients with prolonged disorders of consciousness in Chinese clinical setting.

The existence of fluctuating in arousal is common in patients with prolonged disorders of consciousness; thus, the behavioral response after noxious stimulus of each patient was assessed by two raters within an interval of 6 hours. Moreover, in this study, two raters did not share their results or impressions of each patient to obtain a more reliable reliability. We found a higher inter-rater agreement for Nociception Coma Scale–Revised total scores and subscores compared to several previous studies (e.g. Schnakers et al.¹² ($k=0.61$), Vink et al.²³ ($k=0.62$), and Riganello et al.²⁴ ($k=0.57$)), but similar rate with Sattin et al.²⁵ (using Kendall's W coefficient of concordance; $W=0.90$). Furthermore, good to high reliability rates were also found for each of the subscores. The present study obtained a consistent inter-rater agreement, which suggested that the Chinese version of Nociception Coma Scale–Revised scores collected from different trained evaluators is reliable for each patient with prolonged disorders of consciousness within one day.

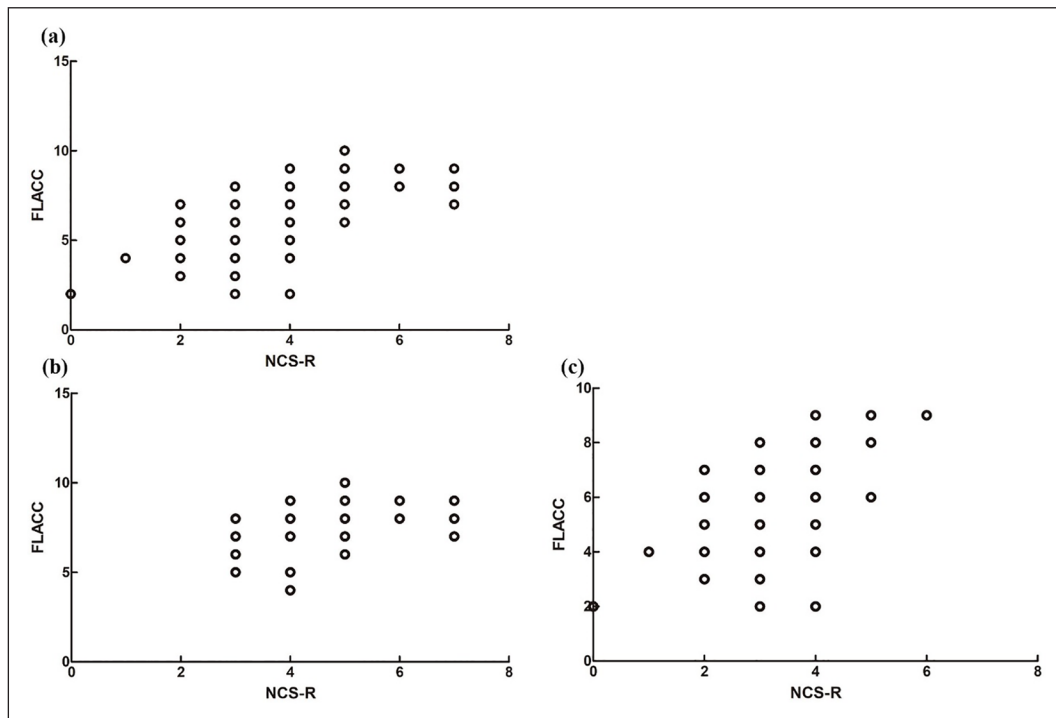


Figure 2. The relationship between the score of Nociception Coma Scale–Revised and the score of the Face, Legs, Activity, Cry, and Consolability behavioral scale total score for (a) all patients with prolonged disorders of consciousness, (b) patients with minimally conscious state, and (c) patients with unresponsive wakefulness syndrome.

NCS-R: Nociception Coma Scale–Revised; FLACC: the Face, Legs, Activity, Cry, and Consolability.

In order to get more stable and reliable results, this study used a larger sample to evaluate reliability and validity of Nociception Coma Scale–Revised. It still found that the agreement was more robust in the test–retest comparison with respect to the observer comparison, which approved that the Chinese version of Nociception Coma Scale–Revised can yield reproducible results over a short period. The test–retest reliability was substantial for total scores ($k=0.66$) from a previous study validation.²⁴ The results of the Italian version of the Nociception Coma Scale–Revised was good for total scores ($ICC=0.79$) and moderate for motor subscale ($r=0.60$) in the test–retest reliability analysis. For the verbal and facial subscales, the test–retest reliabilities were excellent ($r=1.0$).²⁵ In this study, test–retest reliability analysis showed high consistency of the Chinese version scale between

total scores ($ICC=0.971$), which showed a higher agreement than previous studies.

In terms of the internal reliability for the Nociception Coma Scale total scores, this study got similar results with a previous finding by Vink et al.²³ ($\alpha=0.61$). As indicated by the results, this scale only had a moderate internal consistency. However, this internal consistency was acceptable for the limited number items of the Nociception Coma Scale–Revised. Moreover, in this study, all patients were also assessed by the Face, Legs, Activity, Cry, and Consolability behavioral scale, which has been found to be accurate for use with children and persons who are unable to speak in intensive-care units.²⁶ After analyzing these data, it obtained strong concurrent validity between the Nociception Coma Scale–Revised and the Face, Legs, Activity, Cry, and Consolability behavioral

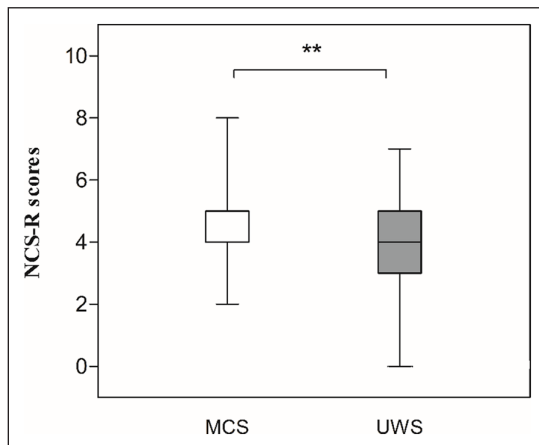


Figure 3. Boxplot of Nociception Coma Scale–Revised scales of patients with minimally conscious state (in white) and unresponsive wakefulness syndrome (in gray). Black lines represent the medians of the Nociception Coma Scale–Revised scores, boxes represent the inter-quartile range, and bars represent minimums and maximums.

NCS-R: Nociception Coma Scale–Revised; MCS: minimally conscious state; UWS: unresponsive wakefulness syndrome.

** $P < 0.001$.

scale on total score. These results demonstrated that the Chinese version of Nociception Coma Scale–Revised constitutes a sensitive and valid tool to assess the responses associated with pain in patients with prolonged disorders of consciousness.

This study also replicated previous findings of a good correlation between Nociception Coma Scale–Revised and Coma Recovery Scale–Revised total scores^{27,28} and an effect of the level of consciousness (i.e. patients with minimally conscious state showing higher scores of Nociception Coma Scale–Revised than unresponsive wakefulness syndrome showing).^{10,12,25,28,29} It further showed that the Nociception Coma Scale–Revised could be a good measure of awareness and that the Coma Recovery Scale–Revised would be helpful in pain management. Actually, the Nociception Coma Scale–Revised is a crude measurement, recording responses that might indicate pain and that are associated with pain experience in those patients who are unable to report it, but it cannot be known whether the patient is actually experiencing pain.

In clinical settings, the decisions on treatment need to take into account many other considerations, not least the sedating effects of most painkillers such that if the patients have consciousness, it is likely to be lost when the analgesic medication is given. Furthermore, some behavioral responses to pain stimuli were still under research, and it is not definitely associated with pain. Clinicians therefore should not give patients sedating and painkilling drugs routinely without thought. Thus, it might be helpful in managing the apparent pain responses in clinical setting. Besides, the Nociception Coma Scale–Revised should not be abused clinically, and the results should not be interpreted separately, but should be combined with other assessment results, such as the Coma Recovery Scale–Revised.

The present study also had several limitations. First, it scored only behavioral responses with the Nociception Coma Scale–Revised during noxious stimuli; it did not evaluate the responses at baseline and during non-noxious stimuli in the present study. Thus, future research could compare pain response during these three conditions (baseline, non-noxious, and noxious stimuli). Second, the study only used the Face, Legs, Activity, Cry, and Consolability behavioral scale as the external independent validation of whether or not the person was experiencing pain. Future studies could use other scales and imaging tools as the external independent validation of Nociception Coma Scale–Revised. Third, it only applied painful stimuli to the limbs, and could not really judge the pain elsewhere. The motor response really only applies to pain given to the limb; the visual response only applied to specific pain localized in a limb. Future investigation should be done to assess the pain elsewhere.

In conclusion, the results of the present study demonstrated that the Chinese version of Nociception Coma Scale–Revised is a useful tool to meet the requirement for clinicians to evaluate responses to pain. In addition, the scores were stable across multiple measurements, and the scale can be reliably administered by various trained members of the clinical staff. Therefore, the Chinese validation of Nociception Coma Scale–Revised can substantially contribute to improving

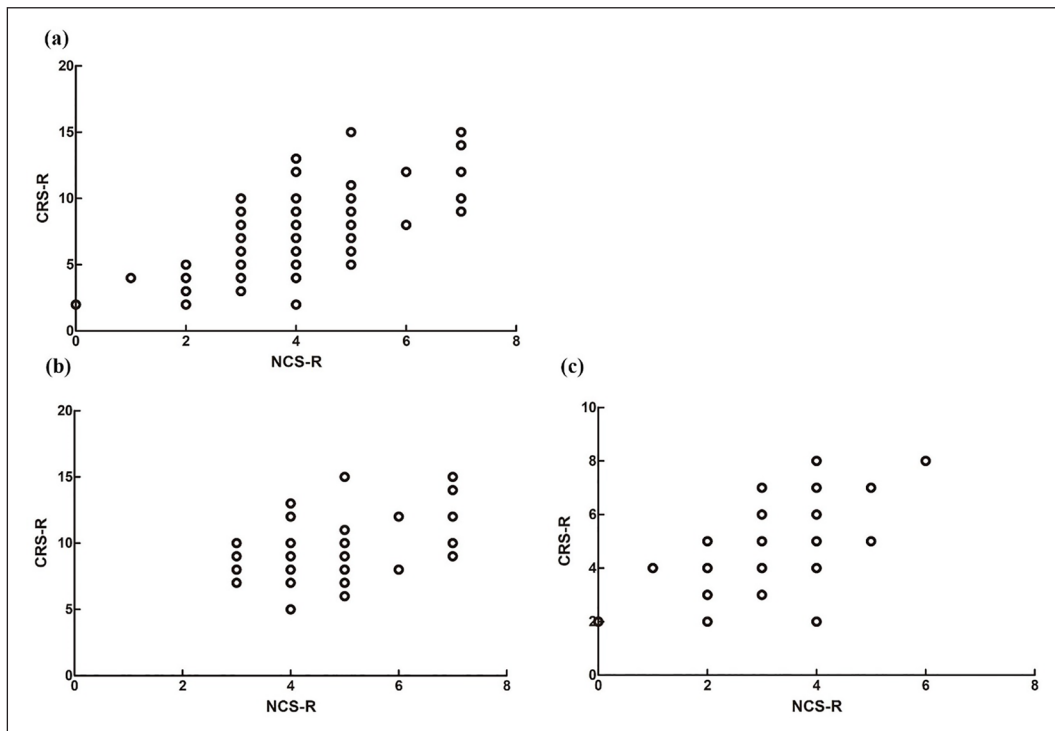


Figure 4. The relationship between the score of Nociception Coma Scale–Revised and the score of Coma Recovery Scale–Revised total score for (a) all patients with prolonged disorders of consciousness, (b) patients with minimally conscious state, and (c) patients with unresponsive wakefulness syndrome. NCS-R: Nociception Coma Scale–Revised; CRS-R: Coma Recovery Scale–Revised.

the clinical pain management of patients with prolonged disorders of consciousness. Having this assessment tool available will be useful for future scientific research regarding pain and will be helpful in promoting the scale in other regions.

Clinical messages

- The Nociception Coma Scale–Revised was translated and now available for Chinese clinicians.
- The Chinese version of the Nociception Coma Scale–Revised is a reliable and valid tool on the measurement of pain responsiveness in patients with prolonged disorders of consciousness.

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Declaration of Conflicting Interests

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Trial registration

This study has been registered in a clinical trials registration, and the Clinical Trials.gov number is NCT03494218. Date of registration: 09 April 2018.

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Supplemental material

Supplemental material for this article is available online.

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